



## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2005-0253; FRL-9329-8]**

#### **Propylene Oxide; Proposed Tolerance Actions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to establish the tree nut crop group tolerance and separate tolerances on pistachio and pine nuts for both the fumigant propylene oxide and the reaction product from the use of propylene oxide, known as propylene chlorohydrin, to cover all registered uses on raw and processed nuts. Also, in accordance with current Agency practice, EPA is proposing minor revisions to tolerance expressions and specific tolerance nomenclatures for propylene oxide and propylene chlorohydrin.

**DATES:** Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2005-0253, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

*Instructions:* Direct your comments to docket ID number EPA-HQ-OPP-2005-0253. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Joseph Nevola, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; e-mail address: [nevola.joseph@epa.gov](mailto:nevola.joseph@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II.A. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

## **II. Background**

### *A. What Action is the Agency Taking?*

In this action, EPA is proposing to amend the propylene oxide tolerance regulation at 40 CFR 180.491 to add the crop group for tree nuts (nut, tree, group 14). In the Reregistration Eligibility Decision (RED) for propylene oxide, the Agency recommended that a tree nut crop group tolerance be established for two separate reasons:

1. As a technical correction to conform the existing tolerance on “nutmeat, processed, except peanuts” with current Agency commodity terms; and

2. To address the lack of a tolerance for registered uses on raw nuts. U.S. EPA, RED for Propylene Oxide (August 2006). In the **Federal Register** of September 24, 2008 (73 FR 54954) (FRL-8382-2), EPA addressed the commodity conformity issue by replacing the “nutmeat, processed, except peanuts” with a tree nut crop group. However, a propylene oxide registrant objected to this action pointing out that this was not merely a technical correction to commodity terms but actually a substantive change to the tolerance because the tree nut crop group did not cover all nuts falling within the generic term “nutmeat, processed.” Accordingly, EPA, on its initiative, corrected its error and replaced the tree nut crop group with the pre-existing tolerance for “nutmeat, processed, except peanuts” in the **Federal Register** of June 29, 2011 (76 FR 38036) (FRL-8877-7). Unfortunately, at the time of that action, EPA failed to recognize that the RED had found that a tree nut crop group was needed both as a technical, conforming change and to cover registered uses on raw nuts. Today, EPA is addressing the second reason by once again proposing to establish a tree nut group tolerance for propylene oxide in 40 CFR 180.491(a)(1) for residues of propylene oxide in or on nut, tree, group 14 at 300 ppm and in 40 CFR 180.491(a)(2) for residues of propylene chlorohydrin in or on nut, tree, group 14 at 10.0 ppm. However, because the current tree nut group tolerance does not cover all registered uses on nuts, EPA is also proposing to establish individual tolerances on these use sites (pistachios, pine nuts) in 40 CFR 180.491(a)(1) for residues of propylene oxide in or on pistachio at 300 ppm and nut, pine at 300 ppm, and in 40 CFR 180.491(a)(2) for residues of propylene chlorohydrin in or on pistachio at 10.0 ppm and nut, pine at 10.0 ppm. Establishment of tolerances for pistachios, pine nuts, and the nut, tree, group 14, would complete the actions recommended by the Agency in the RED.

In order to conform to current Agency practice, EPA is proposing to revise the commodity terminology in 40 CFR 180.491(a)(1) from “herbs and spices, group 19, dried” to “herbs and spices, group 19, dried leaves” and in 40 CFR 180.491(a)(2) from “herbs and spices, group 19, dried, except basil” to “herbs and spices, group 19, dried leaves, except basil.”

Also, in accordance with current Agency practice to describe more clearly the measurement and scope or coverage of tolerances, including applicable metabolites and degradates, EPA is proposing minor revisions to tolerance expressions for propylene oxide and propylene chlorohydrins. The revisions will not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerance.

The Agency is proposing to revise the introductory text containing the tolerance expressions in 40 CFR 180.491(a)(1) and (a)(2).

EPA is required to determine whether each of the amended tolerances meets the safety standard of FFDCA. The safety finding determination of “reasonable certainty of no harm” is discussed in detail in each RED for the active ingredient. REDs recommend the implementation of certain tolerance actions, including modifications to reflect current use patterns, meet safety findings, and change commodity names and groupings in accordance with new EPA policy. Printed copies of many REDs may be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), P.O. Box 42419, Cincinnati, OH 45242-2419; telephone number: (800) 490-9198; fax number: (513) 489-8695; Internet at <http://www.epa.gov/ncepihom> and from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161;

telephone number: (800) 553-6847 or (703) 605-6000; Internet at <http://www.ntis.gov>.

An electronic copy of the propylene oxide RED and its addendums are available on the Internet in the docket for this proposed rule, ID number EPA-HQ-OPP-2005-0253, at <http://www.regulations.gov> and at <http://www.epa.gov/pesticides/reregistration/status.htm>.

Copies of the Residue Chemistry Chapter and other documents (such as the dietary exposure analysis of October 2011 for use of propylene oxide on pine nuts and comprehensive dietary exposure analysis of June 2006) which support the propylene oxide RED are found in the Administrative Record. An electronic copy of the Residue Chemistry Chapter and addendum as well as other support documents for propylene oxide are available through EPA's electronic docket and comment system, [regulations.gov](http://www.regulations.gov) at <http://www.regulations.gov>. You may search for docket ID number EPA-HQ-OPP-2005-0253, then click on that docket ID number to view its contents.

EPA has determined that the aggregate exposures and risks are not of concern for the above mentioned pesticide active ingredients based upon the data identified in the RED which lists the submitted studies that the Agency found acceptable.

*B. What is the Agency's Authority for Taking this Action?*

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA of 1996, Public Law 104-170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a



tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore “adulterated” under section 402(a) of FFDCA, 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce (21 U.S.C. 331(a)). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under FIFRA (7 U.S.C. 136 *et seq.*). Food-use pesticides not registered in the United States must have tolerances in order for commodities treated with those pesticides to be imported into the United States.

The Agency's evaluation of the database for pesticides, including requirements for additional data on the active ingredients to confirm the potential human health and environmental risk assessments associated with current product uses, are contained in REDs, as are the Agency's conditions under which these uses and products will be eligible for reregistration. In REDs, the Agency recommends the establishment, modification, and/or revocation of specific tolerances. The Agency's tolerance recommendations, such as establishing or modifying tolerances, and in some cases revoking tolerances, are the result of assessment under the FFDCA standard of “reasonable certainty of no harm.” However, tolerance revocations recommended in REDs do not need such assessment when the tolerances are no longer necessary.

### *C. When Do These Actions Become Effective?*

EPA is proposing that the establishment of tolerances, and revision of tolerance expressions and nomenclatures become effective on the date of publication of the final rule in the **Federal Register**. If you have comments, please submit comments as described under **SUPPLEMENTARY INFORMATION**.

Any commodities listed in this proposal treated with the pesticides subject to this proposal, and in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(1)(5), as established by FQPA. Under this unit, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and
2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

### **III. International Residue Limits**

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for propylene oxide or propylene chlorohydrin.

#### **IV. Statutory and Executive Order Reviews**

In this proposed rule, EPA is proposing to establish tolerances under FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted this type of action (e.g., establishment of a tolerance) from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5

U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, or expansion of exemptions might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis for tolerance establishments and modifications was published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticide involved in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the

preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.”

“Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 14, 2011.

Steven Bradbury,

*Director, Office of Pesticide Programs.*

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section §180.491 is amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

**§180.491 Propylene oxide; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of the fumigant propylene oxide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only propylene oxide, when used as a postharvest fumigant, in or on the commodity.

| Commodity                                | Parts per million |
|--|-------------------|
| Cacao bean, dried bean                   | 200               |
| Cacao bean, cocoa powder                 | 200               |
| Fig                                      | 3.0               |
| Garlic, dried                            | 300               |
| Grape, raisin                            | 1.0               |
| Herbs and spices, group 19, dried leaves | 300               |
| Nut, pine                                | 300               |
| Nut, tree, group 14                      | 300               |
| Nutmeat, processed, except peanuts       | 300               |
| Onion, dried                             | 300               |
| Pistachio                                | 300               |
| Plum, prune, dried                       | 2.0               |

(2) Tolerances are established for residues of the reaction product, propylene chlorohydrin, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of propylene chlorohydrin (1-chloro-2-

propanol), and its isomer 2-chloro-1-propanol, calculated as the stoichiometric equivalent of propylene chlorohydrin (1-chloro-2-propanol), that results from the use of propylene oxide as a postharvest fumigant, in or on the commodity.

| Commodity  | Parts per million |
|--|-------------------|
| Basil, dried leaves                                    | 6000              |
| Cacao bean, dried bean                                 | 20.0              |
| Cacao bean, cocoa powder                               | 20.0              |
| Fig  | 3.0               |
| Garlic, dried  | 6000              |
| Grape, raisin  | 4.0               |
| Herbs and spices, group 19, dried leaves, except basil | 1500              |
| Nut, pine  | 10.0              |
| Nut, tree, group 14                                    | 10.0              |
| Nutmeat, processed, except peanuts                     | 10.0              |
| Onion, dried   | 6000              |
| Pistachio  | 10.0              |
| Plum, prune, dried                                     | 2.0               |

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